PRIA Fee Category Table – Antimicrobials Division – New Active Ingredients

Table 7.

EPA No.	New CR No.	Action	Decision Review Time (Months)[HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-active-ingredients" \l "footnote1"]	FY'17 & FY'18 Registration Service Fee ($)
[HYPERLINK "http://www2.epa.gov/pria-fees/a380-pria-fee-category"]	71	New Active Ingredient; Indirect Food use; establish tolerance or tolerance exemption if required [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-active-ingredients" \l "footnote2"] [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-active-ingredients" \l "footnote3"]	24	137,841
[HYPERLINK "http://www2.epa.gov/pria-fees/a390-pria-fee-category"]	72	New Active Ingredient; Direct Food use; establish tolerance or tolerance exemption if required [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-active-ingredients" \l "footnote2"] [HYPERLINK "http://www2.epa.gov/	24	229,733

EPA No.	New CR No.	Action	Decision Review Time (Months)[HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-active-ingredients" \l "footnote1"]	FY'17 & FY'18 Registration Service Fee ($)
		pria-fees/pria-fee-category-table-antimicrobial-division-new-active-ingredients" \l "footnote3"]		
[HYPERLINK "http://www2.epa.gov/pria-fees/a410-pria-fee-category"]	73	New Active Ingredient Non-food use[HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-active-ingredients" \l "footnote2"] [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-active-ingredients" \l "footnote3"]	21	229,733
[HYPERLINK "http://www2.epa.gov/pria-fees/a431-pria-fee-category"]	74	New Active Ingredient, Non-food use; low-risk [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-active-ingredients" \l "footnote2"] [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-antimicrobial-division-new-active-ingredients" \l "footnote3"]	12	80,225

[1]A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day.

[2]All requests for new uses (food and/or nonfood) contained in any application for a new active ingredient or a first food use are covered by the base fee for that new active ingredient or first food use application and retain the same decision time review period as the new active ingredient or first food use application. The application must be received by the agency in one package. The base fee for the category covers a maximum of five new products. Each application for an additional new product registration and new inert approval that is submitted in the new active ingredient application package or first food use application package is subject to the registration service fee for a new product or a new inert approval. All such associated applications that are submitted together will be subject to the new active ingredient or first food use decision review time. In the case of a new active ingredient application, until that new active ingredient is approved, any subsequent application for another new product containing the same active ingredient or an amendment to the proposed labeling will be deemed a new active ingredient application, subject to the registration service fee and decision review time for a new active ingredient. In the case of a first food use application, until that first food use is approved, any subsequent application for an additional new food use or uses will be subject to the registration service fee and decision review time for a first food use.

Any information that (a) was neither requested nor required by the Agency, and (b) is submitted by the applicant at the applicant's initiative to support the application after completion of the technical deficiency screening, and (c) is not itself a covered registration application, must be assessed 25% of the full registration service fee for the new active ingredient or first food use application.

[3]Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.